

REMARKS

After entry of this Amendment, the pending claims are: claims 1-16 and 21-40. The Office Action dated May 29, 2007 has been carefully considered. Claims 15, 28 and 33 have been amended. Claims 3-6 and 8 were previously withdrawn as being drawn to a non-elected species. Claims 17-20 have been canceled. No new matter has been added. Reconsideration and allowance of the present application in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated May 29, 2007, the Examiner:

- rejected claims 1, 2, 7, 14-16, 24, 25, 27-33 and 40 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Appln. No. US 2002/0022846 (U.S. Patent No. 5,547,794 B2) to Auge II ("Auge II") in view of U.S. Patent No. 4,430,760 to Smestad ("Smestad").
- rejected claim 28 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,652,593.

INDEPENDENT CLAIM 1

Independent claim 1 has been rejected as being unpatentable over Auge II in light of Smestad. As an initial matter, it is respectfully submitted that the Examiner has not identified any reason why a person of ordinary skill in the art would combined Auge II with Smestad other than it would teach all of the elements of independent claim 1. (*See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, at 1741 (2007) "[a] patent composed of several elements is not proved obvious merely by demonstrating that each

element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.”) It is respectfully submitted that the Applicants through their own effort and expense derived the device as claimed in independent claim 1. It is respectfully submitted that without the benefit of the Applicants’ disclosure, it would not be obvious for one of ordinary skill in the art to redesign the method disclosed in Auge II to incorporate, *inter alia*, the step of wetting a block of cancellous bone so that the bone may be compressed from a first geometry to a second geometry and hardening the block after it has been compressed. If anything, the method of fusion disclosed in Auge II discourages the step of hardening or drying a block of cancellous bone after compression, as the method is performed *in vivo*, in a fluid medium.

Even assuming that the Examiner’s combination of Auge II and Smestad is correct, which in our opinion it clearly is not, the combination still would not disclose, teach or suggest all of the limitations of independent claim 1. Independent claim 1 requires, *inter alia*, the steps of demineralizing a block of cancellous bone, wetting the block, compressing the block from a first geometry to a second geometry smaller than the first geometry, and hardening the block after the block has been compressed to the second geometry.

Auge II discloses a method of fusing bone *in vivo* and in a fluid medium. The method disclosed by Auge II comprises the steps of harvesting implant bone, treating areas of bone to demineralize them, adding an interfacing agent (*e.g.*, a coating) to the implant and receiving bone to facilitate bone fusion,

and applying electromagnetic energy to fuse and/or compress the demineralized bone. (Auge II col. 10, line 64 – col. 11, line 33)

Smestad discloses an implantable bone prosthesis containing bone powder contained in a porous casing. The implant is manufactured by first cleaning bone material to be used in the implant, fragmenting the bone into small pieces, washing and drying the small pieces of bone, grinding the pieces of bone into powder, demineralizing the bone powder with acid, washing the bone powder to remove excess acid, and drying the bone powder. The bone powder is then placed into a porous casing and the casing is sealed. At this point, the implant is now ready for implantation in the patient. (Smestad at col. 2, lines 5-59) The powder-filled casing disclosed by Smestad is flexible and deformable, allowing it to be inserted to fit an implant site. Smestad further discloses that a dry implant should be wetted before it is implanted. (Smestad at col. 4, lines 6-10)

Neither Auge II nor Smestad discloses the step of wetting the block of cancellous bone so that it can be compressed from a first geometry to a second geometry. It is respectfully submitted that Smestad disclosed wetting bone powder for the purpose of removing absorbed acid. Auge II does not disclose wetting a block of demineralized bone for the purpose of compressing the block from a first geometry to a second geometry. Moreover, neither Auge II nor Smestad discloses the step of hardening the block after the block has been compressed from a first geometry to a second geometry.

Therefore, for at least the reasons identified above, it is respectfully submitted that Auge II, either alone or in combination with Smestad, does not disclose, teach, or suggest all of the limitations of

independent claim 1. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2, 7 and 9-14 all depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2, 7 and 9-14 is also respectfully requested.

Moreover, claims 3-6 and 8 were withdrawn as being directed to a non-elected species. It is respectfully submitted that independent claim 1 is generic and, as such, claims 3-6 and 8 should be allowed as well.

INDEPENDENT CLAIM 15

Independent claim 15 has been rejected as being unpatentable over Auge II in light of Smestad. Independent claim 15 requires, *inter alia*, the steps of demineralizing a block of cancellous bone, softening the block so that the block may be compressed from a first geometry to a second geometry smaller than the first geometry, permitting the block to harden after the block has been compressed, inserting the block into a cavity, and re-expanding the block to a third geometry larger than the second geometry.

For at least the reasons identified above in connection with independent claim 1, it is respectfully submitted that Auge II and Smestad, taken together, do not teach, disclose, or suggest the hardening of a block of cancellous bone after it has been compressed, as required by independent claim 15.

Therefore, it is respectfully submitted that Auge II and Smestad, taken together, do not disclose, teach, or suggest all of the limitations of independent claim 15. Withdrawal of this rejection and allowance of independent claim 15 is respectfully requested.

Furthermore, as claims 16, 17 and 21-27 all depend from independent claim 15, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 16, 17 and 21-27 is also respectfully requested.

INDEPENDENT CLAIM 28

Independent claim 28 has been rejected as being unpatentable over Auge II in light of Smestad. Independent claim 28 requires, *inter alia*, the steps of demineralizing a block of cancellous bone, hydrating the block so that the block may be compressed from a first geometry to a second geometry smaller than the first geometry, and dehydrating the block.

For at least the reasons identified above in connection with independent claim 1, it is respectfully submitted that neither Auge II nor Smestad, alone or taken together, do not teach, disclose, or suggest the limitation of dehydrating of a block of cancellous bone after it has been compressed, as required by independent claim 28.

Therefore, it is respectfully submitted that Auge II and Smestad, taken together, do not disclose, teach, or suggest all of the limitations of independent claim 28. Withdrawal of this rejection and allowance of independent claim 28 is respectfully requested.

Furthermore, as claims 29-40 all depend from independent claim 28, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 29-40 is also respectfully requested.

TERMINAL DISCLAIMER

Moreover, independent claim 28 has been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,652,593.

The Examiner indicated that a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) could be used to overcome the nonstatutory double patenting rejection. Applicants respectfully submit that a terminal disclaimer will be filed, if still necessary, when claim 28 is deemed allowable but for the requirement of a terminal disclaimer.

CONCLUSION

No fee is believed due with this submission. If, however, the Commissioner determines otherwise, the Commissioner is authorized to charge any fees which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

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Respectfully submitted,

/Erik Hanson/

Erik Hanson

Registration No. 60,175

For: Brian M. Rothery

Registration No. 35,340

Attorney for Applicants
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, New York 10038
(212) 806-6114